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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

September 10, 2003

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 2003-DAL-WL-19

WARNING LETTER

Certified Mail
Return Receipt Requested

John D. Devereaux, Owner
Route 2 Box 166-1A
Prague, Oklahoma 74864

Dear Mr. Devereaux:

An investigation performed by the U.S. Food and Drug Administration (FDA) included visits to your cattle buyer/dealer operation located at Prague, Oklahoma, April 22, 2003 through May 6, 2003. The investigation confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused an animal drug to become adulterated under Section 501(a)(5).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On February 1, 2003 you sold a black cow, identified with back tag number 3538, for slaughter as human food at [redacted]. USDA analysis (Laboratory Report # 378572) of tissue samples collected from that animal identified the presence of sulfamethazine at 1.38 ppm in the liver and 0.56 ppm in the muscle. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in edible tissues of cattle. (Title 21, Code of Federal Regulations, Section 556.670). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." Our investigation found that you hold animals under conditions which are so inadequate that medicated animals bearing potentially harmful drug residues may enter the food supply. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling. Your firm does not maintain a system for

assuring that animals medicated by you or prior to your purchase of the animal have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

In addition, you are adulterating the drug [redacted] brand of sulfamethazine that your firm uses on cattle under Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug without following the labeled withdrawal period causes the drug to be unsafe to use within the meaning of Section 512.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Reynaldo R. Rodriguez, Jr., Director, Compliance Branch.

Sincerely yours,

Sylvia G. Lyles

Sent Michael A. Chappell
Dallas District Director

MAC/SLK